



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10137 and CMS-10675]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and

includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Solicitation for Applications for Medicare Prescription Drug Plan 2020 Contracts; Use: Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application. The information will be collected under the solicitation of proposals from PDP, MA-PD, Cost Plan, Program of All Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the

application), (2) support the determination of contract awards. Form Number: CMS-10137 (OMB control number: 0938-0936); Frequency: Yearly; Affected Public: Private Sector (Business or other for-profits, Not-for-Profit Institutions); Number of Respondents: 243; Total Annual Responses: 256; Total Annual Hours: 2,351.08. (For policy questions regarding this collection contact Arianne Spaccarelli, at 410-786-5715.)

2. Type of Information Collection Request: New c (Request for a new OMB control number); Title of Information Collection: Evaluation of the CMS Quality Improvement Organizations: Medication Safety and Adverse Drug Event Prevention; Use: The purpose of this Information Collection Request (ICR) is to collect data to inform the program evaluation of the Centers for Medicare & Medicaid Services (CMS) Quality Improvement Organizations (QIO) current contract known as the 11th Scope of Work (SOW). The current ICR focuses on evaluating one component of the quality improvement activities of the Quality Innovation Network Quality Improvement Organizations (QIN-QIOs) and is part of a larger evaluation of the overall impact of the QIO program. This ICR aims to assess the QIN-QIO Task which focuses on Medication Safety and Adverse Drug Event Prevention. For this evaluation, we are using a mixed-methods design to compare quality improvement activities of community-based pharmacists and physician practices participating in the QIN-QIO program (participating) with those not participating in the QIN-QIO program (non-participating).

As mandated by Sections 1152-1154 of the Social Security Act, CMS directs the QIO program, which is one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries. QIOs are groups of health quality experts, clinicians, and consumers who

work to assist Medicare providers with quality improvement throughout the spectrum of care and to review quality concerns for the protection of beneficiaries and the Medicare Trust Fund. This program is a key component of the U.S. Department of Health and Human Services' (HHS) National Quality Strategy and the CMS Quality Strategy. The work is aligned with the current HHS and CMS administration priorities to empower patients and doctors to make decisions about their health care; usher in a new era of state flexibility and local leadership; support innovative approaches to improve quality, accessibility, and affordability; and improve the CMS customer experience. In the current SOW, 14 QIN-QIOs coordinate the work in 53 U.S. states and territories.

CMS evaluates the quality and effectiveness of the QIO program as authorized in Part B of Title XI of the Social Security Act. CMS created the Independent Evaluation Center (IEC) to provide CMS and its stakeholders with an independent and objective program evaluation of the 11th SOW.

For the program to improve medication safety and prevent adverse drug events (ADEs), QIN-QIOs provide technical assistance to providers, practitioners, organizations offering Medicare Advantage plans under Medicare Part C, and prescription drug sponsors offering drug plans under Part D. ADEs are defined as “injury resulting from medical intervention related to a drug,” and cause the majority of preventable deaths in hospitals. ADEs escalate healthcare costs and utilization, increasing admission and readmission rates, emergency department (ED) visits, and physician visits. ADEs are particularly problematic for older adults who have multiple chronic conditions and interact with many care settings.

Opioid misuse and overdose is a significant cause of ADEs and was declared a public health emergency by the White House in 2017. In 2016, over 14 million Medicare Part D beneficiaries received opioid prescriptions, and many of these beneficiaries received extreme amounts of the drugs. The Medicare population has one of the highest and fastest-growing rates of diagnosed opioid use disorder.

As part of the HHS Opioid Initiative launched in March 2015, CMS developed a multipronged approach to combat misuse and promote programs that support treatment and recovery support services for clinicians, beneficiaries, and families. CMS also worked with HHS and other health agencies to develop a *National Action Plan for Adverse Drug Prevention* (2014). In addition to opioids, the Action Plan focused on ADEs caused by other high-risk medication (HRM) groups: anticoagulants and diabetic medications. Given the burden of ADEs caused by these three classes of drugs, focusing prevention efforts in these areas could have a significant impact on reducing harm and improving population health among Medicare beneficiaries.

The QIO program provides technical assistance to reduce ADEs in beneficiaries resulting from polypharmacy, specifically those who use three or more medications including a prescription in a HRM) drug groups. In the 11th SOW, specific interventions include training providers through Learning Action Networks; developing collaborations among local providers across care settings; providing materials and information resources; and helping providers collect data to monitor prescribing practices.

To evaluate the effectiveness of this program, we will use a mixed method evaluation

combining secondary data analysis of Medicare claims with a community provider survey. We plan to conduct an online survey of 1,200 community-based pharmacists and physician practices. These participants were selected based on their role in prescribing HRM and treating ADEs.

The proposed survey assesses the extent to which the *National Action Plan for Adverse Drug Prevention* strategies have been used, the level of engagement with the QIO, and other influences that can help explain progress towards the goals of the QIN-QIO SOW. The questions used for these constructs related to program and non-program influences have been adopted from previously used and/or validated instruments, including the IEC Nursing Home Survey that was approved under OMB control number 0938-1330.

The survey will also provide estimates of the attribution of the QIN-QIO program for improving ADE prevention, and reported impact of the QIN-QIO program from the perspective of healthcare providers. The perceived influence on quality improvement efforts will be quantified and, along with econometric modeling methods, will be used to assess program attribution. Estimating attribution is a contract requirement for the IEC and helps provide evidence of impact of the QIN-QIO program. Since current analytical methods do not adequately address the overlap of quality improvement initiatives targeting medication safety and ADE prevention, the IEC developed an innovative approach, combining survey input with modeling, to estimate the relative importance of the QIN-QIO program. The concept is supported at the highest level of administration for Quality Improvement at CMS and has been presented at national conferences and to CMS/CCSQ leadership. The survey data is an essential component of this analytic method.

The information collected through the survey will complement the existing data by helping identify factors associated with ADE outcomes of interest from existing data sets such as Medicare claims. For example, claims data can provide information on whether the number of prescriptions for opioids has decreased, but not what has helped to facilitate the decrease. Subsequent to the 60-day Federal Register notice which published on July 20, 2018 (83 FR 34593), the collection instrument was revised to clarify wording on questions, adjust the methods for measuring attribution, and nursing homes were removed from the originally-proposed sample. These changes did not result in changes to burden, as additional respondents will be recruited from the pharmacy and practice settings. Form Number: CMS-10675 (OMB control number: 0938-NEW); Frequency: Annually; Affected Public: Private sector (Business or other for-profits); Number of Respondents: 1,200; Total Annual Responses: 1,200; Total Annual Hours: 300. (For policy questions regarding this collection contact Nancy Sonnenfeld at 410-786-1294.)

Dated: November 26, 2018.

William N. Parham, III,
Director, Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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